REMARKS

Claims 26 to 38 are pending in this application. Claims 1 to 25 have been cancelled. Claims 26, 32, 34, and 36 have been amended. Claim 38 has been added.

The Applicants gratefully acknowledge the suggestions made by the Examiner. The Applicants have incorporated these suggestions where required.

In light of the foregoing amendments to the claims, the Applicants respectfully request that the objections under 37 CFR 1.75(c) and the rejections under 35 USC 112, second paragraph, be reconsidered and withdrawn.

The claims of this application stand rejected as being unpatentable over U.S. Patent No. 5580718 to Resnick et al. ("the Resnick et al. patent") either alone or in view of PCT Publication No. WO 01/37291 A1 to Weindel et al. ("the Geiger et al. patent"). The Examiner states that the Resnick et al. patent teaches all the features of the present invention except for the probe of SEQ. ID. NO. 3, which is provided by the Geiger et al. patent. The Examiner asserts that it would have been obvious to substitute the probe of SEQ. ID. NO. 3, as provided by the Geiger et al. patent, for the probes of the Resnick et al. patent because the Resnick et al. patent teaches that it is suitable to use any probe that hybridizes to a conserved region between the two

primers, and Geiger discloses that the probe of SEQ. ID. NO. 3 is suitable for the detection of HCV nucleic acid.

Absent the Applicants' disclosure, there can be no reasonable expectation that merely substituting the probe of SEQ. ID. NO. 3 for the probes of the Resnick patent would result in successful RT-PCR. Neither cited reference provides the reaction conditions of the present invention. The Applicants respectfully submit that the Examiner in incorrect in stating that Resnick teaches the required assay conditions, reagents, amounts, and labels. For example, Resnick does not provide for the amplification component of the present invention as claimed. Moreover, it is well know, that optimal reaction conditions (incubation times and temperatures, concentration of *Taq* DNA Polymerase, primers, MgCl2, and template DNA) vary greatly depending upon the primers and probe being used. The Applicants have discovered that the combination of primers and probe provided by the present invention may be used for HCV diagnosis with high sensitivity, high specificity, rapid results, and high reproducibility.

The Applicants respectfully request favorable consideration and that this application be passed to allowance.

Respectfully submitted,
LACKENBACH SIEGEL, LLP

Date: January 3, 2003 by:

Thomas Blankinship
Reg. No. 39,909

MARKED-UP VERSION OF AMENDED CLAIMS

26. A method for detecting HCV nucleic acid in a biological sample comprising the steps of:

extracting HCV nucleic acid from a biological sample;

~~reverse transcription of the extracted nucleic acid using the reverse strand primer; and~~

amplifying the HCV nucleic acid using a first primer having the sequence

5'-gcagaaagcgtctagccatggcgt-3' [SEQ. ID. NO. 1]

~~and~~ a second primer having the sequence

5'-ctcgcaagcaccctatcaggcagt-3' [SEQ. ID. NO. 2]

and an amplification component consisting essentially of about 100 to about 200 μM of deoxyribonucleoside triphosphate; about 1 unit to about 2.5 units of Taq polymerase; about 1.5 to about 2.5 mM $MgCl_2$; and an amplification buffer having 10 mM Tris HCl (pH 8.3) and 500mM KCl;

and detecting the HCV nucleic acid using an oligonucleotide probe having the sequence:

5'-gtcgtgcagcctccaggaccc-3' [SEQ. ID. NO. 3]

32. The method according to claim 30, wherein the deoxyribonucleoside triphosphate is selected from the group consisting of: dATP, dCTP, 5MedCTP, dGTP, dITP, TTP, dUTP, and combinations thereof~~, and wherein the deoxyribonucleoside triphosphate is present in an amount of about 100 to about 200 μM~~.

34. The method according to claim 33, wherein the HCV nucleic acid is labeled with fluorescein ~~flourescein~~, and wherein the detectable marker is an anti-fluorescein ~~flourescein~~/horseradish ~~horse-raddish~~ peroxidase conjugate in an amount of about 1 unit to about 4 units.

36. The method according to claim 33, wherein the substrate is present in a volume ~~an amount~~ of about 100 µL.